

**CITY OF BLOOMINGTON
UTILITIES DEPARTMENT**

April 16, 2008

NOTICE OF VIOLATION AND REQUIRED RESPONSE

KP Pharmaceutical Technology, Inc.
Attn: Mr. Raj Mathoru
1212 Rappel Dr.
Bloomington, IN 47404

Dear Mr. Mathoru:

Your facility is subject to 40 Code of Federal Regulation 439 Pharmaceutical Manufacturing Subpart D Mixing/Compounding and Formulation and Subpart E Research and Development. The City of Bloomington Utilities (CBU) initially sent an Industrial User Wastewater Survey and Permit Application on January 10, 2008. An additional copy of the permit application was sent on February 29, 2008 to be completed and returned to CBU within 30 days.

An incomplete survey was received on April 14, 2008. CBU has specifically stated that in order to complete the permitting process, wastewater discharge flow rates are required. Although KP Pharmaceuticals may not directly discharge pharmaceutical products into the sewer system, wastewater is generated during the manufacturing and clean room sanitizing operations.

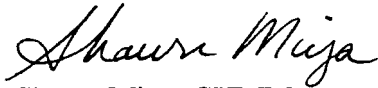
Consequently, you are in violation of Bloomington Municipal Code Chapter 10.16.020 (5) which requires "Disclosure of average daily and instantaneous peak wastewater flow rates, in gallons per day, including daily, monthly and seasonal variations, if any. All flows shall be measured unless other verifiable techniques are approved by the city due to cost or nonfeasibility".

REQUIRED RESPONSE

In order to complete the Industrial User Wastewater Survey and Permit Application, submit a completed Water Use & Disposal Worksheet found in Part III. This information must be submitted to the City of Bloomington Utilities (CBU) **within 10 days**. Failure to submit the required information within the due date may result in Significant Noncompliance Status and administrative fines of up to \$2,500 per violation may be assessed to KP Pharmaceuticals. Each day of noncompliance shall be considered a separate violation.

I have enclosed a copy of the City of Bloomington Sewer Use Ordinance. If you have any questions or concerns, please contact me at 812-349-3946 or by email at miyas@bloomington.in.gov.

Sincerely,

A handwritten signature in cursive script that reads "Shawn Miya".

Shawn Miya, CHMM
Pretreatment Coordinator
City of Bloomington Utilities Department

Indiana Department of Environmental Management, Natalie Maupin
City of Bloomington Legal Department, Vicki Renfrow
File

Enclosure

PART III, Water Use & Disposal Worksheet:

Water Used for:	Water Usage Avg. gal/day	Water Usage Max. gal/day	Measured	Estimated	Water Disposal Method(s) (See Disposal List Below)	Avg. gal/day	Max. gal/day	Measured	Estimated
1. Process water									
2. Washdown water									
3. Water into product									
4. Air Quality Permitted Units									
5. Domestic - toilets, drinking, café									
6. Cooling water, Process Non-Contact									
7. Boiler / Cooling tower blowdown									
8. Cooling water, HVAC									
9. Other:									
Totals					Totals				

Possible Water Disposal Methods

1. Sanitary sewer, with pretreatment
2. Sanitary sewer, without pretreatment
2. Storm sewer
4. Surface waters of Indiana
5. Evaporation
6. Land applied
7. To groundwater
8. Septic tank
9. Waste haulers (identify)
10. Water into product
11. Include others, if applicable